

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Yukoh Sakata, *et al.*

Serial No.: 10/539,021

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Art Unit: 1615

Examiner: Sasan, Aradhana

Conf. No.: 7382

For: LIGHT-SHIELDING AGENT AND FILM-FORMING COMPOSITION

DECLARATION UNDER 37 CFR §1.132

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

I, Yukoh Sakata, hereby declare and state that:

1) I am a citizen of Japan, residing at 1624 Shimokotachi, Koda-cho, Akitakata-shi, Hiroshima, 739-1195, Japan.

2) I am one of the inventors of the subject application, and I am fully familiar with the subject matter thereof as well as the reference relied upon by the Examiner, i.e., Iwata *et al.* (WO 01/40182), in the prosecution of this application.

3) I obtained a Doctoral degree from Hoshi University, Department of Pharmaceutics, School of Pharmacy, in September, 2007, where I performed kinetic study on crystal water affecting pharmaceutical properties of hydrate and anhydrate tablets.

4) I am currently employed by Wakunaga Pharmaceutical Co., Ltd. I began working for Wakunaga Pharmaceutical Co., Ltd. in April 1992, where I have engaged in research and development relating to formulation development.

5) I conducted the following test in order to ascertain whether or not a white film with a luster could form in the absence of any water-soluble calcium salts in accordance with the cited reference, namely, WO 01/40182 A2 (Iwata *et al.*).

Test 1

Method

Composition (1) was a negative control, which was prepared by dissolving 8 g of hydroxypropylmethyl cellulose (HPMC: manufactured by Shin-Etsu Chemical Co., Ltd.) in 100 g of purified water.

Composition (2) was a positive control, which was prepared by dissolving 8 g of HPMC and 2 g of calcium lactate in 100 g of purified water at room temperature. Calcium lactate is a water soluble calcium salt having a solubility of 4.8 g in 100 g of water at 25 °C.

Composition (3) was a sample, which was prepared by dissolving 8 g of HPMC and 2 g of calcium carbonate (manufactured by Wako Pure Chemical Industries, Ltd.) in 100 g of purified water at room temperature. Calcium carbonate is a water insoluble calcium salt having a solubility of 0.0014 g in 100 g of water at 25 °C.

Each of Compositions (1) to (3) was put in each Petri dish and dried using a hot-air drier at 60°C for 10 hours.

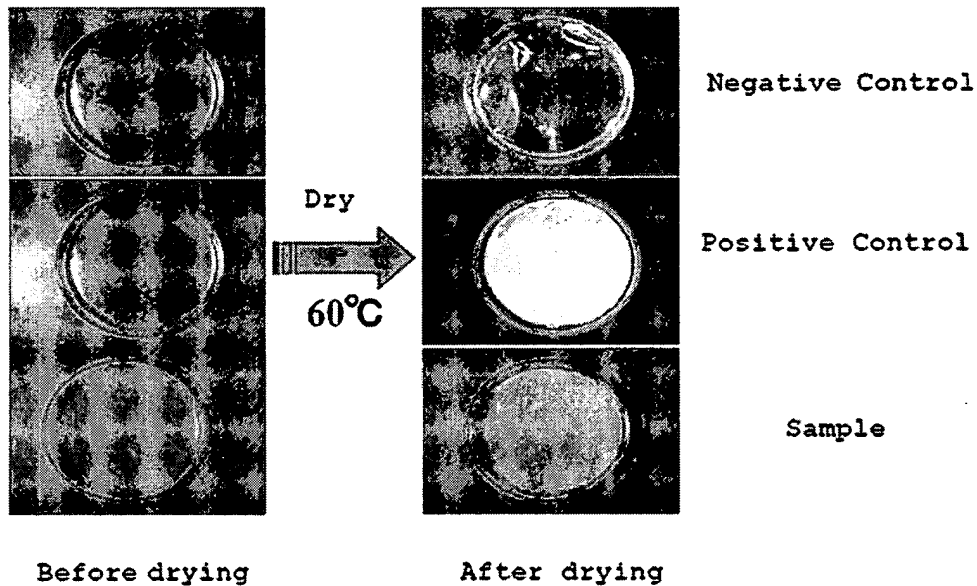
Results

As shown by the following photographs, the negative control (containing only HPMC) was transparent before and after drying. Accordingly, the negative control did not exhibit light-shielding properties.

The positive control (containing both a water-soluble calcium salt and a water-soluble cellulose base polymer in accordance with the present invention) was a transparent solution before drying, but formed a lustered and monolayered white film (in

which the water-soluble calcium salt was uniformly distributed in the water-soluble cellulose base polymer) after drying.

The sample [containing a water-insoluble calcium salt (instead of a water-soluble calcium salt) and a water-soluble cellulose base polymer] before drying was a white suspension (which may cause plugging in a spray nozzle, depositing solid materials at tips of the nozzle, or dropping liquid from the nozzle, if the suspension was coated with a nozzle.). After drying, the sample formed a two-layered uneven film (the upper layer was a HPMC film and the lower layer was formed by agglomerates of calcium carbonate particles).



Conclusion

As demonstrated by the photographs, the combination of the water-soluble calcium salt and the water-soluble cellulose base polymer can provide a lustered white film. Lack of the water-soluble calcium salt or the water-soluble cellulose base polymer would not lead to the formation of the lustered white film with light-shielding properties.

Since no lustered white film could form based on the disclosure of Iwata *et al.*, I believe that the protection of pharmaceutical preparations and compositions from light-irradiation, the suppression of the separation and powder floating on the surface thereof, and maintaining the stability and the quality thereof for a long-term period could not be realized.

6) I fully understand the content of this declaration.

7) I, Yukoh Sakata, the undersigned declarant further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001, of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed this 23 day of February, 2009.

Yukoh Sakata

(Yukoh Sakata)